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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,891	03/17/2004	Christoph Seidel	NY-HUBR 1067.4 DIV	5294

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EXAMINER	
BOESEN, AGNIESZKA	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 09/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/802,891	SEIDEL ET AL.	
	Examiner	Art Unit	
	Agnieszka Boesen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants preliminary amendment filed March 17, 2004 is acknowledged. Applicants comment about current claims 27-30 replacing claims 37-39 and 49 of the parent case 09/896,032 and submission of the Declaration by Dr. Ursula-Henrike Wienhues –Thelen is acknowledged.

Claims 27-30 are pending and under examination.

Priority

Acknowledgment is made for priority to a DIV application, 09/896,032, which is a which is a DIV of 098/892,704, which issued as a US Patent 6,306,579, which is a DIV of 08/511,759 which issued as a US Patent 6,096,319.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 27 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 27 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite and incomplete by omitting essential method steps or ingredients, such omission amounting to a gap between the steps. See MPEP § 2172.01. The claims lack a measurement step or positive process steps to carry out the claimed methods. In the instant case, the claims fail to recite the

steps necessary to carry out the method of determining seroconversion in a human infected with hepatitis C virus. There is lack of recitation of measurement step in which the HCV specific antibody is detected. Lacking enough steps to define a method for determining seroconversion, claims 27 and 28 are incomplete and merely define an immunoassay as presently recited.

While all of the technical details of a method need not be recited, the claims should include enough information to clearly and accurately describe the invention and how it is to be practiced. The minimum requirements for method steps minimally include a contacting step in which the reaction of the sample with the reagents necessary for the assay is recited, a detection step in which the reaction steps are quantified or visualized, and a correlation step describing how the results of the assay allow for the determination.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vallari et al. (Journal of Clinical Microbiology, 1992) in view of Takei et al. (JP06074956).

Claims are drawn to a method for determining seroconversion in a human infected with hepatitis C virus comprising incubating a sample under reducing conditions with at least one

polypeptide derived from hepatitis C virus NS3 protein region to determine hepatitis C virus specific antibody.

Vallari teaches an assay for detection of antibodies to HCV wherein the human sample, containing seroconversion antibodies, is incubated with an NS3 antigen (see the entire document). Vallari further shows detection of seroconversion to anti-HCV in patient samples (see page 554, and Figures 3, 4, and 5).

Vallari does not expressly teach incubating the sample under reducing conditions. Specification defines "reducing conditions" as follows:

[0027] Furthermore in order to avoid the formation of covalently cross-linked molecular aggregates, the immunological test can be carried out under mild reducing conditions (addition of mild reducing reagents, preferably of sulfhydryl reagents, preferably DTT (dithiothreitol) or DTE (dithio-erythritol) in a concentration range of 1 mmol/l to 25 mmol/l).

Takei teaches an assay for detection of HCV specific antibodies using HCV NS3 antigen in presence of a reducing agent, which is the same compound, the DTT (dithiothreitol) or DTE (dithio-erythritol), as the one defined in the current specification (see claims 1-10 of the English translation).

It would have been obvious to the person of ordinary skill in the art to incubate the sample, to be tested for the presence of seroconversion antibodies, under reducing conditions.

One would have been motivated to incubate the sample in Vallari's assay under reducing conditions of Takei, because Takei teaches that a thiol group in cysteine of the NS3 detection antigen is sensitive to natural oxidation, which interferes with antigen activation. Thus, the

treatment of the sample with a reducing agent facilitates antigen activation (see [0008] of English translation).

One would have had a reasonable expectation of success to detect seroconversion antibodies comprising incubating a sample under reducing conditions because the reducing conditions facilitates antigen activation and detection of seroconversion antibodies.

The Declaration of Dr. Ursula-Henrike Wienhues –Thelen has been considered.

- In points 1 and 2 of the Declaration, Dr. Wienhues –Thelen identifies herself as a co-inventor of the claimed subject matter.
- In point 3, Dr. Wienhues –Thelen states that the results in Example 1 and Example 2 of the Declaration, demonstrate that modifying the cysteine residues of the hepatitis C virus polypeptide with a covalent modifying group or replacing cysteine residues of the polypeptide substantially increased the overall sensitivity of the currently claimed method. Dr. Wienhues –Thelen also states that the concentration of releasable sulfhydryl groups of non-modified and modified HCV helicase antigen under reducing conditions may be readily determined, as shown in Example 3.
    - In response, the Office acknowledges the statements of Dr. Wienhues – Thelen and the experimental results. However, it is herein noted that the current claims do not recite covalent modifying or replacing cysteine

residues. Thus the evidence regarding modifying or replacing cysteine residues provided by the Applicant is irrelevant at this point of examination. The current claims do encompass treating HCV NS3 antigen under reducing conditions and this limitation has been found in the prior art as discussed in prior art rejection under 35 U.S.C. 103(a).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnieszka Boesen whose telephone number is 571-272-8035. The examiner can normally be reached on 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AB

Agnieszka Boesen, Ph.D.
Examiner
9/14/06

Stacy B. Chen 9/15/06
STACY B. CHEN
PRIMARY EXAMINER